



Patent Docket P1746R1P1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Vanessa Chisholm et al. Serial No.: 10/714,000 Filed: November 14, 2003 For: EXPRESSION VECTORS AND METHODS	Group Art Unit: To Be Assigned Examiner: To Be Assigned Confirmation No: To Be Assigned CUSTOMER NO: 09157
	CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 2 2004 <i>T. S. Marrs</i> Tom Marrs

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

37 CFR §1.97(b)

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

37 CFR §1.97(c)

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of

allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

37 CFR §1.97(d)

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

37 CFR §1.97(e) Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.

37 CFR §1.704(d) Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.

The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified). A copy of the items on PTO-1449 is supplied herewith. U.S. patents and patent applications are not included. Pursuant to a Patent Office waiver signed July 11, 2003, applicants are no longer required to submit copies of United States patents cited in information disclosure statements for applications filed after June 30, 2003 (**1276 OG 55**). A copy of the International Search Report for the corresponding PCT application is enclosed herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior

application Serial No. 10/019,586, filed December 20, 2001 and relied upon in this application for an earlier filing date under 35 USC §120.

A concise explanation of relevance of the items listed on PTO-1449 is:

- not given
- given for each listed item
- given for only non-English language listed item(s) [Required]
- in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

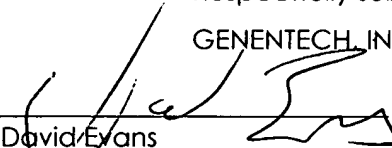
The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630.

Respectfully submitted,

GENENTECH, INC.

Date: April 2, 2004

By:


David Evans
Reg. No. *

Telephone No. (650) 225-1739

* A copy of a document pursuant to 37 C.F.R. §10.9(b) is attached as proof of the authorization of the above to prosecute the attached application. The original of this document is on file in the Office of enrollment and Discipline.



**BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE
UNITED STATES PATENT AND TRADEMARK OFFICE**

LIMITED RECOGNITION UNDER 37 CFR § 10.9(b)

David Evans is hereby given limited recognition under 37 CFR § 10.9(b) as an employee of Genentech, Inc. to prepare and prosecute patent applications in which Genentech, Inc. is the assignee of record of the entire interest. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) David Evans ceases to lawfully reside in the United States, (ii) David Evans's employment with Genentech, Inc. ceases or is terminated, or (iii) David Evans ceases to remain or reside in the United States on an H1B visa.

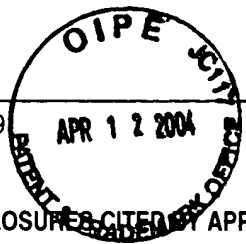
This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the United States Patent and Trademark Office.

Expires: May 1, 2004

A handwritten signature in black ink, appearing to read "Harry L. Moatz", written over a horizontal line.

Harry L. Moatz

Director of Enrollment and Discipline



FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.
P1746R1P1

Serial No.
10/714,000

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant
Crowley et al.

Filing Date
14 Nov 2003

Group
Not yet available

U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date
	1	4,399,216	16.08.83	Axel et al.		
	2	4,634,665	06.01.87	Axel et al.		
	3	4,713,339	15.12.87	Levinson et al.		
	4	5,491,084	13.02.96	Chalfie et al.		
	5	5,561,053	01.10.96	Crowley		
	6	5,625,048	29.04.97	Tsien et al.		
	7	5,777,079	07.07.98	Tsien et al.		
	8	5,795,737	18.08.98	Seed et al.		
	9	5,804,387	08.09.98	Cormack et al.		
	10	5,874,304	23.02.99	Zolotukhin et al.		

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation		
						Yes	No	
	11	0 711 835 A	15.05.96	EP				
	12	WO 92/08796	29.05.92	PCT				
	13	WO 94/28143	08.12.94	PCT				
	14	WO 95/21191	10.08.95	PCT				
	15	WO 96 04391 A	15.02.96	PCT				
	16	WO 97/42320	13.11.97	PCT				
	17	WO 98/06737	19.02.98	PCT				
	18	WO 98/21355	22.05.98	PCT				

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

19	Bennett et al., "Fusion of green fluorescent protein with the zeocin-resistance marker allows visual screening and drug selection of transfected eukaryotic cells" <u>Biotechniques</u> 24(3):478-482 (Mar 1998)
20	Chalfie et al., "Green Fluorescent Protein as a Marker for Gene Expression" <u>Science</u> 263:802-805 (1994)
21	Chishima et al., "Cancer Invasion and Micrometastasis Visualized in Live Tissue by Green Fluorescent Protein Expression" <u>Cancer Research</u> 57:2042-2047 (May 15, 1997)
22	Crameri et al., "Improved Green Fluorescent Protein by Molecular Evolution Using DNA Shuffling" <u>Nature Biotechnology</u> 14:315-319 (1996)
23	Cubitt et al., "Understanding, improving and using green fluorescent proteins" <u>Trends Biochem. Sci.</u> 20:448-455 (1995)
24	Davies et al., "The Sequence Context of the Initiation Codon in the Encephalomyocarditis Virus Leader Modulates Efficiency of Internal Translation Initiation" <u>Journal of Virology</u> 66:1924-1932 (1992)
25	Gubin et al., "Long-Term, Stable Expression of Green Fluorescent Protein in Mammalian Cells" <u>Biochem. Biophys. Res. Commun.</u> 236:347-350 (1997)
26	Heim et al., "Improved green fluorescence" <u>Nature</u> 373:663-664 (1995)

Examiner	Date Considered
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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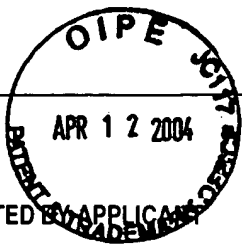
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

27	Hung et al., "Molecular cloning of the neu gene: Absence of gross structural alteration in oncogenic alleles" <u>Proc. Natl. Acad. Sci. USA</u> 83:261-264 (1986)
28	Jang et al., "Initiation of Protein Synthesis by Internal Entry of Ribosomes into the 5' Nontranslated Region of Encephalomyocarditis Virus RNA In Vivo" <u>Journal of Virology</u> 63(4):1651-1660 (1989)
29	Johnston and Kucey, "Competitive Inhibition of hsp70 Gene Expression Causes Thermosensitivity" <u>Science</u> 242:1551-1554 (1988)
30	Kaetzel and Nilson, "Methotrexate-induced Amplification of the Bovine Lutropin Genes in Chinese Hamster Ovary Cells" <u>Journal of Biological Chemistry</u> 263(13):6344-6351 (1988)
31	Kaufman and Schimke, "Amplification and Loss of Dihydrofolate Reductase Genes in a Chinese Hamster Ovary Cell Line" <u>Molecular & Cellular Biology</u> 1(12):1069-1076 (1981)
32	Kaufman and Sharp, "Amplification and Expression of Sequences Cotransfected with a Modular Dihydrofolate Reductase Complementary DNA Gene" <u>J. Mol. Biol.</u> 159:601-621 (1982)
33	Kaufman et al., "Coamplification and Coexpression of Human Tissue-Type Plasminogen Activator and Murine Dihydrofolate Reductase Sequences in Chinese Hamster Ovary Cells" <u>Molecular & Cellular Biology</u> 5(7):1750-1759 (1985)
34	Kaufman et al., "Translational Efficiency of Polycistronic mRNAs and Their Utilization to Express Heterologous Genes in Mammalian Cells" <u>EMBO Journal</u> 6(1):187-193 (1987)
*35	Kaufman <u>Genetic Engineering</u> , J. Setlow, New York:Plenum Press Vol. 9 (1987)
36	Kaufman, "Selection and Coamplification of Heterologous Genes in Mammalian Cells" <u>Methods in Enzymology</u> 185:537-566 (1990)
37	Levenson et al., "Internal Ribosomal Entry Site-Containing Retroviral Vectors with Green Fluorescent Protein and Drug Resistance Markers" <u>Human Gene Therapy</u> 9:1233-1236 (1998)
38	Lubiniecki and Lupker, "Purified Protein Products of rDNA Technology Expressed in Animal Cell Culture" <u>Biologicals</u> 22(2):161-169 (1994)
39	Lucas et al., "High-Level Production of Recombinant Proteins in CHO Cells Using a Dicistronic DHFR Intron Expression Vector." <u>Nucleic Acids Research</u> 24(9):1774-1779 (1996)
40	Marshall et al., "The Jellyfish Green Fluorescent Protein: A New Tool for Studying Ion Channel Expression and Function" <u>Neuron</u> 14:211-215 (1995)
41	Meng et al., "Green fluorescent protein as a second selectable marker for selection of high producing clones from transfected CHO cells" <u>Gene</u> 242:201-207 (2000)
42	Moir and Mao, "Protein Secretion Systems in Microbial and Mammalian Cells" <u>Bioprocess. Technol.</u> 9:67-94 (1990)
43	Mosser et al., "Use of a dicistronic expression cassette encoding the green fluorescent protein for the screening and selection of cells expressing inducible gene products" <u>Biotechniques</u> 22:150-161 (1997)
44	Nataranjan et al., "Comparison of mutant forms of the green fluorescent protein as expression markers in Chinese hamster ovary (CHO) and <i>Saccharomyces cerevisiae</i> cells" <u>J. Biotechnol.</u> 62:29-45 (1998)
45	Nolan et al., "Fluorescence-activated cell analysis and sorting of viable mammalian cells based on B-D-galactosidase activity after transduction of <i>Escherichia coli</i> lacZ" <u>Proc. Natl. Acad. Sci. USA</u> 85:2603-2607 (1988)
46	Olson et al., "Analysis of MAP4 Function in Living Cells Using Green Fluorescent Protein (GFP) Chimeras" <u>Journal of Cell Biology</u> 130:639-650 (1995)

Examiner

Date Considered

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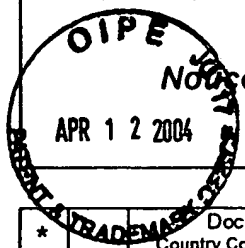
Group
Not yet available

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

47	Pelletier et al., "Internal initiation of translation of eukaryotic mRNA directed by a sequence derived from poliovirus RNA" <u>Nature</u> 334:320-325 (1988)
48	Prasher et al., "Primary structure of the Aequorea victoria green-fluorescent protein" <u>Gene</u> 111:229-233 (1992)
49	Primig et al., "A novel GFPneo vector designed for the isolation and analysis of enhancer elements in transfected mammalian cells" <u>Gene (Amsterdam)</u> 215:181-189 (Jul 17, 1998)
50	Ringold et al., "Co-expression and Amplification of Dihydrofolate Reductase cDNA and the Escherichia coli XGPRT Gene in Chinese Hamster Ovary Cells" <u>Journal of Molecular & Applied Genetics</u> 1(3):165-175 (1981)
51	Schimke, R., "Gene Amplification in Cultured Cells" <u>Journal of Biological Chemistry</u> 263(13):5989-5992 (May 1988)
52	Simonsen and Levinson, "Isolation and Expression of an Altered Mouse Dihydrofolate Reductase cDNA" <u>Proc. Natl. Acad. Sci. USA</u> 80(9):2495-2499 (1983)
53	Urlaub et al., "Deletion of the Diploid Dihydrofolate Reductase Locus from Cultured Mammalian Cells" <u>Cell</u> 33:405-412 (1983)

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Application/Control No. 10/019,586	Applicant(s)/Patent Under Reexamination CHISHOLM ET AL.	
Examiner Ray Akhavan	Art Unit 1636	Page 1 of 1

U.S. PATENT DOCUMENTS

* A-M	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
A	US-			
B	US-			
C	US-			
D	US-			
E	US-			
F	US-			
G	US-			
H	US-			
I	US-			
J	US-			
K	US-			
L	US-			
M	US-			

FOREIGN PATENT DOCUMENTS

* N-T	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
N					
O					
P					
Q					
R					
S					
T					

NON-PATENT DOCUMENTS

* U-X	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
U	Chishima et al. Cancer Research, May 15, 1997, 57:2042-47.
V	Meng et al. Gene, Jan. 2000, 242:201-7.
W	Moir and Mao. Bioprocess. Technol., 1990, 9:67-94.
X	Lubiniecki and Lupker. Biologicals, 1994,22(2): 161-9.

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.